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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,366	12/21/2001	Olga Bandman	PF-0349-2 CON	4978

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EXAMINER	
BASI, NIRMAL SINGH	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,366	BANDMAN ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *12/21/01*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

2. ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 9-10, 12-13, 46 and 57 drawn to isolated polynucleotide, recombinant polynucleotide, cell transformed with recombinant polynucelotide, method of producing polypeptide, classified in class 435, subclass 69.1.

II. Claims 3-7, 9, 10, 12-13, 46 and 57, drawn to isolated polypeptide, classified in class 530, subclass 350.

III. Claims 11, 31, 32, 34, 36-43 drawn to antibody, classified in class 530, subclass 387.9, for example.

IV. Claim 8 drawn to transgenic organism, classified in class 800, subclass 2, for example.

V. Claims 14-16 drawn to method of detecting polynucleotide using hybridization, classified in class 435, subclass 6, for example.

VI. Claim 19 drawn to method for treating a condition associated with decreased expression of functional RBPhu, comprising administering the polypeptide of claim 17, classified in class 514, subclass 2, for example.

VII. Claim 20 drawn to method of screening a compound for effectiveness as an agonist of a polypeptide of claim 1, comprising detecting agonist activity, classified in class 435, subclass 7.1, for example.

VIII. Claim 21 drawn to the agonist identified by the method of claim 20, class and subclass cannot be defined because the agonist is not disclosed.

IX. Claim 22 drawn to method for treating a condition associated with decreased expression of functional RBPhu, comprising administering the agonist of claim 21, class and subclass cannot be defined because the agonist is not disclosed.

X. Claim 23 drawn to method of screening a compound for effectiveness as an antagonist of a polypeptide of claim 1, comprising detecting agonist activity, class 435 and subclass 7.1.

XI. Claim 24 drawn to the antagonist identified by the method of claim 23, class and subclass cannot be defined because the antagonist is not disclosed.

XII. Claim 25 drawn to method for treating a condition associated with increased expression of functional RBPhu, comprising administering the antagonist of claim 24, class and subclass cannot be defined because the antagonist is not disclosed.

XIII. Claim 26 drawn to method of screening for a compound that specifically binds to the polypeptide of claim 1, the method comprising detecting compound binding to polypeptide, classified in class 435, subclass 7.1, for example.

XIV. Claim 27 drawn to method of screening for a compound that modulates the activity of the polypeptide of claim 1, the method comprising assessing

the activity of the polypeptide in the presence of test compound, classified in class 435, subclass 7.1, for example.

XV. Claim 28 drawn to method of screening a compound for effectiveness in altering expression of a target polynucleotide of SEQ ID NO:2 comprising comparing expression of the polynucleotide in the presence or absence of varying amounts of compound , classified in class 435, subclass 6, for example.

XVI. Claim 29 drawn to method of assessing toxicity of a test compound comprising treating a biological sample containing nucleic acids with test compound and measuring the amount of hybridization complex , classified in class 435, subclass 6, for example.

XVII. Claim 30 drawn to a diagnostic test for a condition or disease associated with the expression of RBPhu in a biological sample comprising combining biological sample with an antibody of claim 11 and detecting the complex formed, classified in class 435, subclass 7.2, for example.

XVIII. Claim 33 drawn to a method of diagnosing a condition or disease associated with the expression of RBPhu in a subject ,comprising administering the labeled antibody of claim 34, classified in class 735, subclass7.2, for example.

XIX. Claim 44 drawn to a method of detecting the polypeptide of SEQ ID NO:1 using the antibody of claim 11, comprising detecting specific binding of

antibody with polypeptide, classified in class 435, subclass 7.2, for example.

XX. Claim 45 drawn to a method of purifying the polypeptide of SEQ ID NO:1 using the antibody of claim 11, comprising detecting binding of antibody with polypeptide and separating the antibody from the sample and obtaining purified polypeptide, classified in class 530, subclass 412, for example.

XXI. Claims 48-55 drawn to an array comprising a first oligonucleotide or polynucleotide sequence specifically hybridizable with at least 30 contiguous nucleotides of a target polynucleotide of claim 12, classified in class 536, subclass 24.31.

The inventions are distinct, each from the other because of the following reasons.

Inventions I-IV, VIII, XI, and XXI are patentably distinct products.

The polypeptide of group II and polynucleotide of group I are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. The polynucleotide of group I does not encode the Ab of groups III, agonist of group IV, antagonist of group XI. The polynucleotide of group I is

structurally and functionally different to that of group IV and XXI. The information provided by the polynucleotide of group I can be used to make a materially different compounds eg antibodies. The nucleic acid of group XXI which hybridizes to target polynucleotide of claim 12, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with SEQ ID NO. 1. The polypeptide of group II can made by chemical synthesis or can be recovered from a natural source by using biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. Further the polypeptide of group II and the antibody of group III are patentably distinct for the following reasons:

While the inventions of both group II and group III are polypeptides, in this instance the polypeptide of group II is a single chain molecule that functions as an enzyme, whereas the polypeptide of group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group II and the antibody of group III are structurally distinct molecules; any relationship between a polypeptide of group II and an antibody of group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptide of group II is a large molecule which contains potentially hundreds of regions to which an antibody may bind, whereas the antibody of group III is defined in terms of its binding specificity to a small structure within SEQ ID NO: 1. Thus immunization with the polypeptides of group II would result in the production of antibodies outside the scope of group III. Furthermore, an antibody of group III would not specifically bind all of the polypeptides of group II because the polypeptides of group II are not required to include residues of SEQ ID NO :1 to which the antibody binds. Therefore the polypeptide and antibody are patentably distinct.

Further, the agonist and antagonist of groups VIII and XI are not disclosed and would be expected to divergent in structure than the compounds of inventions I-IV, VIII, XI, and XXI. Also the agonists and antagonist can be used to produce antibodies which are completely unrelated to those produced by the products of groups I-IV, and XXI . The inventions of groups I-IV, VIII, XI, and XXI are all structurally and functionally different and capable of separate use and manufacture.

Furthermore, searching the inventions of group I-IV, VIII, XI, and XXI would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. Groups I-IV, VIII, XI, and XXI all require different searches eg amino acid sequence, polynucleotide search, organic/inorganic structure or literature search

Inventions V-VII, IX- XI, XII-XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04,

MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The methods of groups V-VII, IX- XI, XII-XX are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for practicing the inventions differ significantly. The final analysis step is different for each group. Therefore, each method is divergent in materials and steps. For these reasons the Inventions V-VII, IX- XI, XII-XX are patentably distinct.

Furthermore, the distinct steps of the methods of Groups V-VII, IX- XI, XII-XX require separate and distinct searches. As such, it would be burdensome to search the inventions of Groups V-VII, IX- XI, XII-XX together.

The invention of Group I and the methods of Groups V, XV, XVI, XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of group I can be used to make recombinant proteins.

Searching the inventions of Groups I and V together would impose serious search burden. The inventions of Groups I and V have a separate status in the art as shown by their different classifications.

Inventions of Group II and the methods of Groups VI, VII, IX, X, XIII, XIV, XVII, XVIII, XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used to make antibodies.

Inventions of Group III and the methods of Groups XVII, XVIII, XIX, XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used to secondary antibodies which bind the antibody of Group III, said antibodies being useful in diagnostic assays.

The product of Inventions III and the methods of Groups VI, IX-XV are unrelated because the product of group III is not used or otherwise involved in the process of group VI, IX-XV.

The product of Inventions IV and the methods of Groups V-VII, IX-X, XII-XX are unrelated because the product of group IV is not used or otherwise involved in the process of group V-VII, IX-X, XII-XX.

Inventions of Group VIII and the methods of Groups VII, IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the agonist can be used to produce antibodies.

The product of Inventions VII and the other methods climed, except the methods of Groups VII, IX , are unrelated because the product of group IV is not used or otherwise involved in the process of said groups.

Inventions of Group XI and the methods of Groups X, XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antagonist can be used to produce antibodies.

The product of Inventions XII and the other methods claimed, except the methods of Groups X, XIII are unrelated because the product of group IX is not used or otherwise involved in the process of said groups.

Inventions of Group XXI and the methods of Groups XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group XXI can be used to purify DNA.

The product of Inventions XXI and the other methods claimed, except the methods of Groups XXI are unrelated because the product of group IX is not used or otherwise involved in the process of said groups.

Searching the inventions of Groups I –XXI, in any combination together, would impose serious search burden.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C.

101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal s. Basi
Art unit 1646
September 29, 2004

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